Reply to Office Action of December 31, 2008

REMARKS

Docket No.: 341148004US2

Claims 98-107 are presently pending in this application. Claims 98, 102-107 have been amended to clarify certain features of these claims, and without prejudice to pursuing these claims in unamended or other forms in a continuation or other application. No claims have been cancelled or added in this response.

In the Office Action mailed November 29, 2007, claims 98-107 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,611,700 issued to Vilsmeier et al ("Vilsmeier") in view of U.S. Patent No. 5.377.678 issued to Dumoulin et al ("Dumoulin") and/or US Publication No. 2003/0192557 issued to Krag et al ("Krag"). With respect to the Krag reference, applicants appreciate the Examiner's comments in the Response to Arguments section of the Office Action noting that the Krag reference qualifies under 102(e) and has the same assignee and common inventor. (Office Action, page 7) Further with regard to Krag, applicants acknowledge the Examiner's recommendation of filing a terminal disclaimer to overcome the Krag reference obviousness-type double patenting rejection under 103(c) and note that this rejection is provisional due to the pending nature of the Krag reference. Applicants respectfully request the opportunity to defer filing a terminal disclaimer until all substantive rejections are resolved and, depending on the scope of the claims in the application at that time, applicant will file a terminal disclaimer, if appropriate,

Also in the Office Action, claims 98-107 were provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 and 82-84 of copending Application No. 09/877,498 in view of Vilsmeier. Attached herewith is a terminal disclaimer in compliance with 37 C.F.R. 1.321. Accordingly, applicants respectfully submit that this rejection should be withdrawn.

As a preliminary matter, applicants wish to thank Examiners Winakur and Rosanski for their willingness to engage in a productive Examiner's Telephone Interview on February 3, 2009. During the telephone conference, we discussed some of the distinctions between the pending claims and the teaching of Vilsmeier and Dumoulin. In particular, we believe we reached agreement that the claim amendments proposed herein overcome all outstanding prior art rejections. Accordingly, applicants request that this paper constitute the applicants' Interview Summary. If the Examiner notices any deficiencies in this regard, he is encouraged to contact the undersigned attorney to correct such deficiencies.

Docket No.: 341148004US2

Response to the Section 103(a) Rejection of Vilsmeier in view of Dumoulin or Krag

Claims 98-107 were rejected under 35 U.S.C. §103(a) as being unpatentable over Vilsmeier in view of Dumoulin or Krag. As described below, the combination of Vilsmeier and Dumoulin fails to disclose or describe several of the features of these claims.

> 1. Claim 98 is Directed to An Apparatus for Locating an Tracking a Treatment Target in a Patient for Use in Connection with a Radiation Delivery System Including, inter alia, a Wireless Marker Configured to be Implanted in the Patient at a Site Relative to a Treatment Target Wherein the Marker is Energized or Excited by An Excitation Source Positioned Exterior of the Patient

Claim 98 is directed to a control system for locating and tracking a treatment target in a patient. The apparatus includes a wireless marker configured to be implanted in the patient at a site relative to the treatment target wherein the marker is energized or excited by an excitation source positioned exterior of the patient. The apparatus further includes a sensor that obtains position information about the location and/or orientation of the marker and a computer operatively coupled to the sensor. The computer having a computer operable medium containing instructions that cause the computer to (a) receive the position information from the sensor, (b) determine an actual location of the treatment target, (c) compute a displacement between the treatment target and a beam isocenter of the radiation beam, and (d) automatically control the radiation beam and/or move the patient support based on the computed displacement between the treatment target and the beam isocenter.

Vilsmeier Discloses an Apparatus for Positioning a Body for Radiation
Using an Implanted Flexible Position Sensor, Such as a Glass Fiber Cable

Docket No.: 341148004US2

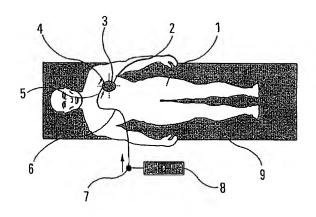


Figure 1 from US Patent No. 6,611,700 (Vilsmeier)

Reply to Office Action of December 31, 2008

Vilsmeier discloses a method and apparatus for positioning a body for radiation. With reference to Figure 1 shown above, the apparatus includes a glass fiber cable 6, serving as the flexible position sensor, attached by its outer end 7 to a controller 8 so that the position and directional vector of the outgoing glass fiber cable 6 is clearly defined by a connecting point serving as a fiducial point to permit obtaining definite information as regard the location of a specific point or of several points, preferably as regards the location or curvature of the glass fiber 6 as a whole using this fiducial point. The other end of the glass fiber cable 6 or position sensor is introduced into the body of the patient 1 and fixedly anchored in the site of the tumor. (Vilsmeier, col. 4-5, lines 62-67 and 1-5) The glass fiber cable 6 can be suitably curved, for example, during insertion in the tissue, so as to steer the glass fiber cable 6, e.g. around a bone. (Vilsmeier, Figure 2, col. 5, lines 34-37)

3. <u>Dumoulin Discloses a Tracking System for Tracking an Invasive Device</u>

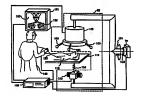


Figure 1 from US Patent No. 5,377,678 (Dumoulin)

Dumoulin discloses a tracking system in which radiofrequency signals emitted by an invasive device, such as a catheter, are detected and used to measure the position and orientation of the invasive device. With reference to Figure 1, Dumoulin disclosed a support arm 101 capable of being rotated about an axis 102 and translated by gantry control means 70. Support arm 101 holds X-ray source 103 and also holds an X-ray

detection means 105 aligned with the propagation of X-rays 104 emitted by X-ray source 103. X-rays 104 penetrate a subject support table 110 and a subject 112. An invasive device 120 is placed inside the subject by an operator 140. The location of the invasive device 120 is visible on the display means 150 driven by a tracking/display unit 108. Invasive device 120 is modified to incorporate a small RF transmit coil (not shown in Figure 1). The transmit coil may be attached to several invasive devices. The signals detected by received coils 160 are used by tracking/display unit 108 to calculate the position and orientation of the transmit coil (and therefore invasive device 120).

Docket No.: 341148004US2

4. The Combination of Vilsmeier and Dumoulin Fails to Disclose or Suggest at least an Apparatus for Use in Connection with a Radiation Delivery System Including, inter alia, a Wireless Marker Configured to be Implanted in the Patient at a Site Relative to a Treatment Target, Wherein the Marker is Energized or Excited by An Excitation Source Positioned Exterior of the Patient

Independent claim 98 is patentable over the combination of Vilsmeier and Dumoulin because these references fail to disclose or suggest at least an apparatus for use in connection with a radiation delivery system including, "wireless marker configured to be implanted in the patient at a site relative to a treatment target, wherein the marker is energized or excited by an excitation source positioned exterior of the patient."

Vilsmeier fails to teach or disclose a wireless marker and a sensor that obtains position information about the location and/or orientation of the marker. Vilsmeier discloses an implantable position sensor. Vilsmeier therefore neither needs nor discloses a wireless marker, which is configured such that it is energized by an excitation source positioned exterior of the patient and does not physically connect with an outside energy source, and a corresponding external sensor for obtaining position information about the orientation and/or location of the wireless marker. Vilsmeier fails

Reply to Office Action of December 31, 2008

Docket No.: 341148004US2

to disclose a claimed element, namely, a wireless marker, therefore Vilsmeier fails to anticipate or render obvious the claimed invention.

Further, as recognized by the Examiner and in contrast to the wireless transponder feature of claim 98, the flexible position sensor of Vilsmeier is an implanted glass fiber cable, which is connected by wires to a controller, thereby not transmitting information wirelessly. (Office Action Dated December 31, 2008; page 4) However the Examiner then incorrectly concludes that "because Vilsmeier teaches that alternative sensors capable of providing three-dimensional information are suitable for use in their arrangement" the tracking system of Dumoulin can be combined with the teachings of Vilsmeier to yield the claimed invention. (Office Action dated December 31, 2008; page 4) The applicants respectfully disagree.

Vilsmeier does not teach or disclose that any alternative sensor would work with the disclosed invention, rather Vilsmeier teaches and discloses flexible position sensors to include glass fiber cable, flexible cable or tape-type sensors "of which it is possible to detect the run of the sensor cable three-dimensionally on the basis of the signals output by the sensor. Thus, e.g. the curvature of the sensor at any desired point along its contour may be detected so that one or more fiducial points on the sensor can be easily detected which can be brought into a position relative to a tissue to be irradiated which does not shift out of place or only negligibly so." (col. 2, lines 16-27) Accordingly, Vilsmeier's teaching of a flexible position sensor having a contour which may be detected teaches away from a wireless marker which is energized or excited by an excitation source positioned exterior of the patient.

Moreover, Dumoulin fails to cure the failure of Vilsmeier to teach or suggest a wireless maker <u>and</u> a sensor or any of the other above-noted deficiencies of Vilsmeier to properly support a *prima facie* case of obviousness. For example, Dumoulin fails to disclose an implantable marker and a sensor for wirelessly tracking the marker. Further, Dumoulin fails to provide a motivation for replacing the flexible position sensor

Docket No : 341148004LIS2

of Vilsmeier with the tracking system of Dumoulin, and also fails to teach or suggest a wireless tracking system wherein the marker is energized or excited by an excitation source positioned exterior of the patient. Furthermore, applicants believe that substituting the tracking system of Dumoulin with the flexible position sensors of Vilsmeier as suggested by the Examiner may actually destroy the functionality taught and disclosed by Vilsmeier, namely, wherein a curvature of the flexible position sensor may be detected at a given point along the sensor length. Accordingly, the combination of Vilsmeier and Dumoulin fails to disclose or suggest all of the features of claim 98, and therefore, the Section 103(a) rejection of claim 98 should be withdrawn.

Claims 99-107 depend from or include features generally analogous to the features of claim 98. Accordingly, the Section 103(a) rejection of claims 99-107 should be withdrawn for at least the reasons discussed above with reference to claim 98 and for the additional features of these claims.

Davco/McKesson Disclosure

In accordance with the undersigned's current understanding of the obligations imposed by *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F 3d. 1358 (Fed. Cir. 2003) and *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897 (Fed. Cir. 2007), the file histories of the following applications may contain information material to one or more of the pending claims. In assessing the patentability of the pending claims, the Examiner is respectfully requested to review the file history of each of the listed applications, determine whether such applications have "similar subject matter" and, if so, consider each substantive Office Communication and Office Action, including each reference on which a rejection is based, and each paper submitted by applicant therein. If the Examiner requires any further information in this respect, please let the undersigned know.

Application Serial No. 09/877,498, filed on June 8, 2001.

- b. Application Serial No. 10/721.491, filed November 25, 2003.
- c. Application Serial No. 10/743,531, filed November 15, 2003.

Conclusion

In accordance with our Examiner's Interview, the pending claims comply with 35 U.S.C. § 112 and patentably define over the prior art. Applicant accordingly respectfully requests reconsideration of the application and a mailing of a Notice of Allowance. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (206) 359-6088. The Commissioner is authorized to change any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 50-0665, under Order No. 341148004US2 from which the undersigned is authorized to draw.

Dated: 4.30.09

Respectfully submitte

Docket No.: 341148004US2

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